

## **REMARKS**

### **Election/Restrictions**

Claims 71-73 and 80-93 have been withdrawn from consideration as being drawn to a non-elected species of the invention. The Applicant has cancelled claims 80-93 without prejudice for possible submission and consideration in a continuing application. The Applicant has chosen to maintain withdrawn claims 71-73 in the pending application for possible reinstatement upon the allowance of one or more generic base claims.

### **Double Patenting**

Claim 54 has been rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of commonly owned U.S. Patent No. 6,676,665. In response to the obviousness-type double patenting rejection, the Applicant has submitted a Terminal Disclaimer herewith along with the requisite fee, and respectfully requests withdrawal of the double patenting rejection.

### **Claim Rejections – 35 USC §102 and §103**

Claims 54-70 and 75-79 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,995,868 to Brazier and U.S. Patent No. 5,454,365 to Bonutti, and claims 54-58 and 64-76 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,885,258 to Sachdeva. Additionally, claim 74 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Brazier patent and the Bonutti patent.

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

### **Independent Claims 54 and 75**

Independent claim 54 has been amended to recite, among other elements and features, an elongate member extending along a longitudinal axis and including a deformable distal portion having an initial configuration for placement adjacent a spinal structure and an expanded

configuration wherein the deformable distal portion is outwardly deformed to define at least one transverse projection, with “each of said at least one transverse projection arranged along a single transverse axis, and wherein formation of said transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis” such that at least a portion of the spinal structure is uniaxially displaced along said transverse axis.

Independent claim 75 has been similarly amended to recite, among other elements and features, an elongate member extending along a longitudinal axis and including a deformable distal portion having an initial relaxed configuration for placement adjacent a spinal structure and a stressed configuration wherein the deformable distal portion is outwardly deformed to define at least one transverse projection, with “each of said at least one transverse projection arranged along a single transverse axis, and wherein formation of said transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis” such that at least a portion of the spinal structure is uniaxially displaced along the transverse axis.

The Applicant submits that support for the amendments incorporated into independent claim 54 and 75 is found, for example, in paragraph [0048] of the published application and in Figures 6 and 12.

With regard to the Brazier reference, disclosed therein is a catheter device including an inner tube 10 positioned within an outer tube 12. As illustrated in Figures 2 and as described in the written description, the distal portion of the outer tube 12 is “slit to form a Malecot retaining device i.e. four longitudinal strands 20 which expand outwards to form protruding wings if the inner tube 10 is moved to the left.” (Column 4, lines 38-49; emphasis added). The protruding wings 20 in turn provide a retention structure to anchor the distal portion of the outer tube 12 in soft tissue to maintain the position of the distal portion to effectuate bladder drainage. As should be apparent, outward expansion of the four longitudinal strands correspondingly forms four protruding wings 20 extending radially outward and positioned circumferentially about the distal portion of the outer tube 12.

Even assuming arguendo that the four radially protruding wings 20 could be construed to comprise transverse projections, each of the radially protruding wings 20 are clearly not

“arranged along a single transverse axis”, as recited in independent claims 54 and 75. To the contrary, the four radially protruding wings 20 are arranged along multiple transverse axes. Furthermore, formation of the four radially protruding wings 20 is not directionally controlled such that each of the wings 20 “extends in a uni-axial direction aligned with said single transverse axis” to uniaxially displace at least a portion of a spinal structure along the transverse axis. To the contrary, the four protruding wings 20 extend in multiple radial directions that are clearly not aligned with a single transverse axis. For at least these reasons, the Brazier reference does not disclose each of the elements and features recited in independent claims 54 and 75. Furthermore, the Brazier reference does not in any way suggest and one of ordinary skill in the art would not be motivated to arrange each of the radially protruding wings 20 along a single transverse axis such that each of the wings 20 extends in a uni-axial direction aligned with a single transverse axis. For at least the reasons set forth above, the Applicant submits that independent claims 54 and 75 are patentable over the Brazier reference.

With regard to the Bonutti reference, disclosed therein is a mechanically expandable retractor for use in arthroscopic surgery. The retractor has an expanding portion at its distal end for expanding sub-surface tissue, with the expanding portion including a series of radially expanding arms that are positioned circumferentially about the retractor to expand the sub-surface tissue to provide a working space between adjacent arms. As shown in Figure 1 and 2, the retractor 10 includes an inner retractor body 12 and an outer retractor sleeve 14, with the retractor sleeve 14 having an expanding portion 60 that “includes a plurality of circumferentially spaced expanding arms 62. Adjacent arms 62 define between them a series of slots 64. The expanding portion 60 . . . has eight equally spaced arms 62 over a 360° range. It should be understood that the present invention contemplates that any different number of arms can be used, and they can be spread equally or unequally over a different circumferential extent, in order to provide varying or eccentric expansion.” (Column 4, line 63 to column 5, line 4). Other embodiments of retractor instruments are illustrated in Figures 6-30, each including an outer retractor sleeve that is similarly provided with multiple circumferentially spaced expanding arms that are positioned over different circumferential extents of the outer sleeve.

Even assuming arguendo that the circumferentially spaced expanding arms could be construed to comprise transverse projections, each of the expanding arms are clearly not

“arranged along a single transverse axis”, as recited in independent claims 54 and 75. To the contrary, the expanding arms are arranged along multiple transverse axes. Furthermore, formation of the expanding arms is not directionally controlled such that each of the expanding arms “extends in a uni-axial direction aligned with said single transverse axis” to uniaxially displace at least a portion of a spinal structure along the transverse axis. To the contrary, the expanding arms extend in multiple radial directions which are clearly not aligned with a single transverse axis. For at least these reasons, the Bonutti reference does not disclose each of the elements and features recited in independent claims 54 and 75. Furthermore, the Bonutti reference does not in any way suggest and one of ordinary skill in the art would not be motivated to modify the instrument disclosed therein to arrange the radially expanding arms along a single transverse axis such that each of the expanding arms extends in a uni-axial direction aligned along a single transverse axis. For at least the reasons set forth above, the Applicant submits that independent claims 54 and 75 are patentable over the Bonutti reference.

With regard to the Sachdeva reference, disclosed therein are a number of medical instruments which include distal portions that are deformable to perform various functions. Illustrated in Figures 1A and 1B is a tube 11 having four slots 12 which are provided to create a balloon-shaped structure that can be used as a retrieval basket to capture small particles 14. Figure 2 illustrates a tool for dilation of vessels 24 where the tube 21 and the geometry of the segments 22 determine the magnitude of the dilation force F. Figure 3 illustrates a reamer including multiple cutting elements or edges 32 which remove material from the inner wall of an artery or other tubular cavities. Figure 4 illustrates a micropump for the local injection of a dissolution fluid to dissolve obstructions in arteries or kidney stones. The slotted sections 42 of the tube 41 create a balloon shaped cavity 45 having a specific volume. Figure 5 illustrates a tube 51 having an expanding section 52 containing an optical fiber 56 positioned in the center of the expanding section 52 to enable inspection of the expanded area and adjacent areas. Figure 6A illustrates a tube 61 having slots 65 that provide multiple gripping segments 62 for holding soft tissue. Figures 7A and 7B illustrate similar instruments including a tube 71 having slots 77 that provide multiple gripping segments 72 for holding soft tissue. Figure 8 illustrates an instrument including a tube 81 having a distal tip 82 having a cavity wall 89 that is expanded from a normal diameter  $C_1$  to an expanded diameter  $C_2$  to form an expanded area 87. Figures 9A

and 9B illustrate a tube 91 having a slotted section 92 that is positioned in a fallopian tube or oviduct and expanded to seal a cavity via filling the slotted section 92 of the tube with an elastic polymer 95. Figure 9C illustrates a sterilization device 94 provided by a slotted tube 150 having slots at both ends which provide a plurality of retention elements at each end of the tube. Figure 10A illustrates a tube 101 having an expanding section 102 that acts as a delivery tube for delivering a third tube 107 that contains an optical system 106 for visual inspection of an artery wall 110. Figures 10B and 10C are alternative configurations of the tube 101, but which are provided with the same type of expansion features. Figure 11 illustrates a tube 201 that is provided with slots 202 in a zigzag pattern to enlarge a contraction. Figures 12A and 12B illustrate the cross section of a tubular stent in collapsed and expanded states, respectively.

Even assuming arguendo that the various instrument embodiments disclosed in the Sachdeva reference could be construed to define transverse projections, each of the projections are clearly not “arranged along a single transverse axis”, as recited in independent claims 54 and 75. To the contrary, each of the instrument embodiments are provided with four elements that extend outwardly in radial directions and which are arranged along multiple transverse axes. Furthermore, formation of the radially extending elements is not directionally controlled such that each of the elements “extends in a uni-axial direction aligned with said single transverse axis” to uniaxially displace at least a portion of a spinal structure along the transverse axis. To the contrary, the transverse elements extend in multiple radial directions which are clearly not aligned with a single transverse axis. For at least these reasons, the Sachdeva reference does not disclose each of the elements and features recited in independent claims 54 and 75.

Furthermore, the Sachdeva reference does not in any way suggest and one of ordinary skill in the art would not be motivated to arrange each of the transversely extending elements along a single transverse axis such that each of the elements extends in a uni-axial direction aligned with a single transverse axis. For at least the reasons set forth above, the Applicant submits that independent claims 54 and 75 are patentable over the Sachdeva reference.

For at least the reasons set forth above, independent claims 54 and 75 are submitted to be patentable over the Brazier, Bonutti and Sachdeva references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 54 and 75 and allowance of the same. Claims 55-57 and 59-74 depend either directly or indirectly from independent

claim 54, and claims 76-79 depend either directly or indirectly from independent claim 75. Accordingly, dependent claims 55-57, 59-74 and 76-79 are submitted to be patentable for at least the reasons set forth above in support of the patentability of their respective independent base claims 54 and 75

**Rewritten Independent Claim 58**

The Applicant has rewritten claim 58 in independent form, and has also amended independent claim 58 to recite, among other elements and features, an elongate member extending along a longitudinal axis and including a deformable distal portion having an initial configuration for placement adjacent a spinal structure and an expanded configuration wherein the deformable distal portion is outwardly deformed, and “wherein said expanded configuration defines a single pair of transverse projections arranged generally opposite one another along a single transverse axis, and wherein formation of said pair transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis” such that at least a portion of a spinal structure is uniaxially displaced along the transverse axis. The Applicant submits that support for the amendments incorporated into rewritten independent claim 58 is found, for example, in paragraph [0048] of the published application and in Figures 6 and 12.

As indicated above with regard to independent claims 54 and 78, the Brazier, Bonutti and Sachdeva references fail to disclose or suggest an elongate member including a deformable distal portion that is outwardly deformed to define at least one transverse projection, with “each of said at least one transverse projection arranged along a single transverse axis, and wherein formation of said transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis”. For reasons similar to those set forth above in support of the patentability of independent claims 54 and 75, the asserted references likewise fail to disclose or suggest an elongate member having an expanded configuration which “defines a single pair of transverse projections arranged generally opposite one another along a single transverse axis”, and “wherein formation of said pair transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis.” The Applicant

therefore submits that independent claim 58 is patentable over each of the cited patent references, and respectfully requests withdrawal of the rejection of claim 58 and allowance of the same.

### CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 54-79. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

Brad A. Schepers

Reg. No. 45,431

Krieg DeVault LLP

One Indiana Square, Suite 2800

Indianapolis, Indiana 46204-2079

(317) 238-6334 (voice)

(317) 238-6371 (facsimile)